

### REMARKS

Claims 1-23 are pending in the above-identified application. Claim 1 has been amended substantively in two respects: (1) first, the definition of “X” has been amended to clarify that this substituent represents an “ethenylene” group in the “E” or “Z” configuration, in addition to the “ethynylene” or “bond” alternatives; and (2) second, the term “prodrugs” has been replaced with the more specific definition of this term disclosed in the specification at page 8, line 37 to page 9, line 7 in response to the issues under 35 USC 112 addressed below. Support for the change to “ethenylene” of item (1) is found by reviewing the compounds exemplified in Table 1, pages 21-22, and on pages 48-57, as well as the intermediates shown in the reaction scheme 1 at page 17. Applicant realized that the original term “ethylene” could be interpreted to be interpreted to be a  $-\text{CH}_2-\text{CH}_2-$  group with a single bond, which would be inconsistent with the intended and exemplified meaning of this term.

### Unity of Invention and Election of Species Requirements

The Examiner has required election in the present application between:

Group I -- claims 1-17, directed to compounds and compositions of formula I as in claim 1; and  
Group II -- claims 18-23, directed to methods for treating diseases by using the compounds of the subject matter of Group I.

For the purposes of examination of the present application, Applicant affirms the election, with traverse, of Group I, Claims 1-17. In addition, in response to the Election of Species Requirement, Applicant affirms the provisional election, also with traverse, of Compound 3, corresponding to Example 3. It is noted that claims 1-3, 6, 7, 10, and 12-17 are readable on Compound 3.

The Unity of Invention Requirement is respectfully traversed, since Applicant is entitled to a second invention category, such as claims directed to the use of the elected product, under PCT Administrative Instructions, Annex B, Section (c)(i), pages AI-58 to AI-59 of the MPEP. Further, it is submitted that there is no undue burden placed on the Examiner to additionally examine the subject matter of non-elected Group II.

The Election of Species Requirement is also respectfully traversed, since all of the elected claims 1-17 require the presence of a compound having a core structure defined by formula I, such that all of these claims share a “special technical feature” which defines over the prior art. Thus, it is requested that this Requirement also be withdrawn.

Information Disclosure Statement

Applicant will file an Information Disclosure Statement within the next weeks which provide references cited in the specification, as well as identifies co-pending applications that could potentially be considered to be related to the present application.

Issues under 35 USC 112

Claims 1-17 have been rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement because of the recitation of “prodrugs” in claim 1. As noted above, claim 1 has been amended so as to replace the term “prodrugs” with the more specific definition “*in vivo* hydrolysable esters”. According to this definition, the claimed compounds include hydroxyl group(s) masked as hydrolysable esters which *in vivo* is reconverted to the hydroxyl group(s). Concerning compounds in which A is hydrogen, Applicant respectfully directs the Examiner’s attention to Compound 26 listed in Table 1, page 22 in the specification. In this compound, the “A” substituent is a hydrogen atom. The Examiner also states that there are no compounds prepared which include 16-ene or 19-nor compounds of claim 1. Applicant respectfully disagrees. Compound 24 prepared as described in Example 22 includes a double bond between carbon-16 and carbon-17. Further Compound 22, prepared as described in Example 20, is a 19-nor compound having no substitution at the C-19 carbon.

In view of the above, it is respectfully submitted that the inserted definition satisfies the written description requirement as it reasonably defines a structural genus. Therefore, it is requested that this rejection be withdrawn.

Issues under 35 USC 103(a)

Claims 1-17 have been rejected under 35 USC 103(a) as being unpatentable over Gao '208 (US 6,028,208). This rejection is respectfully traversed based on the following reasons.

The Examiner asserts that Gao '208 teaches compounds which suggest or embrace the compounds of the present invention. Applicant respectfully disagrees. Gao '208 claims vitamin D<sub>3</sub> derivatives which require a substituted (C<sub>5</sub>-C<sub>7</sub>)carbocyclic ring, as at least X and/or Y must be different from hydrogen. Of the claimed compounds in Gao '208, only formula [1]+[1a] or formula [1]+[1b] may constitute an ethenylene group (when A and B express a single bond) between C-20 and the carbocyclic ring as in the present invention. However, the compounds of the present invention do not include substituted (C<sub>5</sub>-C<sub>7</sub>)carbocyclic rings. Further, Gao '208 fails to disclose or suggest to one skilled in the art that the described compounds should be modified to a different structure, let alone to the structure of the presently claimed compounds. Consequently, significant patentable distinctions exist between the present claims and Gao '208 such that the above rejection must be withdrawn.

Responsive to the request by the Examiner to identify the bases for the provisos, it is submitted that: [1] the first proviso disclaims compounds of formula I of WO 95/02577; [2] Applicant has conducted research to determine the second proviso, but has not yet confirmed the basis for it; and [3] the third proviso disclaims "vitamin VIII", disclosed at page 1259 of Bogoslovsky et al. (Proceedings of the Fourth Workshop on Vitamin D, Berlin, West Germany, Feb. 1979, A. W. Norman et al. (Eds.), p. 1257-1259). The Bogoslovsky et al. reference will be submitted in an IDS as noted above.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Andrew D. Meikle, Registration No 32,868, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- ☒ Attached is a Petition for Extension of Time.
- ☒ Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
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